REMARKS

The Applicants respectfully object to the issuance of a Final Office Action because the Examiner cited new grounds for rejecting the claims. The Applicants respectfully request that the Examiner withdraw the finality of the Office Action dated October 19, 2005.

The Applicants are amending Claim 21 to more fully delineate that the whole cell culture of *Fusobacterium necrophorum* is being inactivated and that the inactivated whole cell culture of *Fusobacterium necrophorum* is being used in the vaccine. The Applicants submit that no new matter is being added.

35 U.S.C. § 103(a)

The Examiner rejected Claims 21-22 under 35 U.S.C. § 103(a) as unpatentable over Garcia et al. (Canadian Journal Comp Med., 38:222-226, 1974) in view of Emery et al. (Aust. Vet. J., 1985, Vol 62, No. 2, pp.43-46).

The Examiner believes that Garcia et al. teaches a method of preventing liver abscesses in bovines (Abstract); inactivating *Sphaerophous necrophorus* preparations with formaldehyde to make vaccine compositions (page 223); using alum in the vaccine composition (page 223), using a dosage of 1.0 to 20.0 ml (page 223), injecting the calves subcutaneously in the neck (page 223), administering a boost injection (page 224), and that the vaccine composition containing the cytoplasmic toxoid was most effective in protecting against liver abscesses (page 225).

The Examiner further states that Emery et al. teaches that the gram-negative *Fusobacterium necrophorum* causes foot abscesses and liver abscesses (page 43); that F. necrophorum can be cultured on suitable medium for up to 18 hours (page 44).

The Examiner believes that it would be prima facie obvious at the time of the invention was made to use a vaccine comprising *F. necrophorum* in a method of preventing footrot or liver abscesses because Emery et al. teaches that the association between *F. necrophorum* and lesion of foot abscesses in cattle implies that potential vaccine against infection should be sought from these strains of *F. necrophorum*. Further the Examiner states that it would be expected barring evidence to the contrary that vaccine composition comprising *F. necrophorum* would be effective in preventing infections caused by *F. necrophorum* because Garcia et al. has shown that *F. necrophorum* is effective against preventing *F. necrophorum* infections.

The Applicants respectfully disagree with the Examiner's understanding of Garcia et al. First, Garcia et al. did not use whole cell *F. necrophorum* in the vaccine. Garcia et al. ruptured

the bacteria ultrasonically for 18-20 minutes with a sonic vibrator (see top of second column, page 223). The sonicated cells were centrifuged at 18,000 g for fifteen minutes to separate the supernatant and sediment. "The supernatant was considered to consist of the intracellular or cytoplasmic fraction..." (see top of second column, page 223). Garcia et al. used in the vaccine sonicated cell toxiod, cytoplasmic toxoid (10.5 mg protein), and cytoplasmic toxoid (15.5 mg protein) (see top of first column on page 224).

Garcia et al. used a cytoplasmic extract for the vaccine which contrasts with the present invention which used whole cell bacteria inactivated with formaldehyde. Such formaldehyde inactivation does not permit cytoplasmic proteins from being presented to an animal's immune system. Rather only the proteins on the exterior of the bacteria and those proteins excreted from the bacteria and present in the cell culture.

Furthermore, Garcia et al. teaches away from the present invention of using whole cell inactivated bacteria when it states in the first few sentence of the Discussion section (page 225),

> "[r]esults of this study suggest that cattle may be protected against liver abscesses with the use of *S. necrophorus* **cell extracts**. The **cytoplasmic toxiod** produced the most promising results." [emphasis added]

One skilled in the art would understand Garcia et al. as leading toward a vaccine contained an extract from bacteria cells, namely using the **cytoplasmic** extract, not the whole cell culture inactivated with formaldehyde which does not permit the cytoplasmic proteins from being separated from the bacteria as in the present invention.

Emery et al. fails to provide any remedy for this failure on the part of Garcia et al. Emery et al. does not discuss vaccines; rather Emery covers various physical characteristics of *F. necrophorum*.

Thus Applicants believe that the combination of Garcia et al. and Emery et al. fail to teach a vaccine containing whole cell inactivated bacteria culture as required by Claim 21. As such, the Examiner's rejection of the pending claims under 35 U.S.C. § 103(a) over Garcia et al. in light of Emery et al. is inaccurate and requests withdrawal of this rejection.

The Examiner also rejected pending Claims 21-22 under 35 U.S.C. § 103(a) as unpatentable over Garcia et al. (Canadian Journal Comp Med., 38:222-226, 1974) in view of Clark et al. (Aust. Vet. J. April 1986, 63(4): 107-10).

The Examiner recites the teaches of Garcia et al as mentioned above. The Examiner cites Clark et al has teaching that *F. necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (Abstract); whole culture vaccine compositions (page 107-108); that the vaccine composition containing culture supernatants provide the most protection against footrot in cattle (Abstract and page 109); and that *F. necrophorum* can be cultured for up to 18 hours.

The Examiner believe that it would have been prima facie obvious at the time of the invention to add the vaccine compositions of culture supernatants of *F. necrophorum* at taught by Clark et al. to the vaccine compositions comprising *F. necrophorum* cytoplasmic toxoid of Garcia et al. to be used to prevent footrot and liver abscesses in cattle because Garcia et al. has demonstrated that compositions comprising *F. necrophorum* cytoplasmic toxoid are effective at preventing liver abscesses in cattle and Clark et al. has demonstrated that compositions comprising *F. necrophorum* culture supernatants are effective in preventing footrot in cattle. The Examiner believes that barring evidence to the contrary, vaccine compositions containing *F. necrophorum* cytoplasmic toxoid and culture supernatants would be effective in preventing infections caused by *F. necrophorum.*

The Applicants respectfully disagree with the Examiner's reading of Garcia et al. and the Examiner's conclusions.

As stated above, Garcia et al. used sonicated bacteria to make a vaccine (see top of second column, page 223). Garcia et al. found at the cytoplasmic toxiod vaccine was most promising (page 225). Garcia is teaching the use of a cytoplasmic toxoid, one devoid of the cell wall components. This cytoplasmic toxoid provided more favorable results (1.4 or 2.0 abscesses per infected liver) than the vaccine made from sonicated bacteria which had been inactivated with formulin and precipitated with alum (7.0 abscesses per infected liver) (see Table 1, and footnote d of Table 1 on page 225). As such, Garcia et al. seems to teach away from using a vaccine containing whole cell bacteria and cell culture toxoids.

Furthermore, because Garcia et al. does not teach using whole cell bacteria culture vaccine, the fact that Garcia et al. injected its vaccine subcutaneously and the dosage volume are irrelevant to the present discussion. The dosage volume and route of administration is highly dependent on the type of vaccine used. To assume that a cell extract vaccine administered subcutaneously in a certain dosage would apply to a whole cell bacteria culture vaccine is simply inaccurate.

There is no teaching in Clark et al. that remedies the deficiencies of Garcia et al. In Table 1 on page 109, Clark et al. demonstrates that its preparation of concentrated whole culture of *F. necrophorum* was less efficacious than concentrated *F. necrophorum* culture supernatant fluid (18 out of 28 feet infected compared to 15out of 28 feet infected) in Experiment 1. In Experiment 3, the concentrated culture supernatant was much more effective than the concentrated killed washed *F. necrophorum* cells. If one skilled in the art would combine Clark et al. with Garcia et al., then one would believe that a vaccine containing the concentrated cell culture supernatant and the cytoplasmic proteins would be a good vaccine. In contrast, the present invention uses the cell culture (not concentrated) and whole cell bacteria, both inactivated with formaldehyde, as a vaccine.

Because the combination of Garcia et al. and Clark et al. teaches the use of cytoplasmic fraction of bacteria with concentrated cell culture supernatant rather than the use of whole cell bacteria and un-concentrated cell culture as in the present invention, Garcia et al. and Clark et al. fail to make a prima facia case of obviousness for the presently claimed invention. In conclusion, the Applicants request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection for the pending claims.

Potential 35 U.S.C. § 102(b) Rejection

The undersigned recognizes that the U.S. has established a Duty of Candor under 37 C.F.R. § 1.56 when dealing with the USPTO. As such, the undersigned would like to provide the Examiner with the following information.

The earliest priority date of this patent application and its parent, U.S. Patent 6,632,439, is September 29, 1999. Gary A. Anderson, Douglas L. Stine, and Adrian Liem, the inventors, signed an oath before a notary public that the invention claimed in the patent application was not on sale or in public use more than a year prior to the filing date of the patent application. The inventors worked for ImmTech Biologics, LLC, at the time of the conception and reduction to practice of the invention disclosed and claimed in this patent application and its parent, U.S. Patent 6,632,439, and when the first patent application for this invention was filed with the USPTO.

On June 19, 1999, ImmTech Biologics, LLC, filed an application with the USPTO for trademark registration of the mark "FUSOGARD" which is the commercial name of the vaccine covered by this patent application and U.S. Patent 6,632,439. According to the trademark application, the date of first use in interstate commerce of the mark "FUSOGARD" is "during June 1998", and labels were submitted as specimen of the mark. One of the inventors for this patent application, Gary A. Anderson, signed the Declaration for the trademark application for "FUSOGARD". A copy of the trademark application is enclosed. The USPTO granted this application for trademark registration.

If the application for registration of the trademark "FUSOGARD" is correct, the mark was first used in interstate commerce more than one year prior to the filing date of the patent application. This seems to indicate that the invention covered by U.S. Patent 6,632,439 and this pending patent application was sold more than one year prior to the earliest priority date of U.S. Patent 6,632,439 and this pending patent application.

The undersigned is unable to explain this apparent discrepancy. An investigation into this discrepancy is on-going.

The inventors have not provided the undersigned with information which explains this apparent discrepancy.

The undersigned is providing this information to the Examiner in order to comply with the requirements of 37 C.F.R. § 1.56.

Should the Examiner have any questions or believes that an interview would be useful for the prosecution of this application, the Examiner is requested to contact the undersigned at the telephone number indicated.

Respectfully submitted,

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David L. Marks
Attorney for Applicants
Reg. No. 37,881

Date: January 12, 2006

06-04-1999

U.S. Patent & TMOfc/TM Mail Rcpt Dt. #34

Applicant:	Immtech Biologics, LLC
P.O. Address:	8600 W. 239 Bucyrus, Kansas 66013
First Use:	On the goods, during June, 1998 in commerce regulated by Congress, during June, 1998
Goods:	Animal Vaccines

FUSOGARD

TRADEMARK

75721668

LAW OFFICES
HOVEY, WILLIAMS, TIMMONS & COLLINS
A PARTNERSHIP OF PROFESSIONAL CORPORATIONS
ESTABLISHED 1929
INTELLECTUAL PROPERTY LAW EXCLUSIVELY
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June 1, 1999

Box New Appl. - Fee
Assistant Commissioner for Trademarks
2900 Crystal Drive
Arlington, VA 22202-3513

Dear Sir:

Enclosed herewith please find complete application for registration of the mark FUSOGARD on behalf of Immtech Biologics, LLC.

The registration fee of $245.00 filing fee in the form of a check from the attorneys in the case is enclosed herewith. In the event any additional fees are required, please charge the same to our Deposit Account No. 19-0522.

Please forward the filing receipt to this office at your early convenience.

Sincerely yours,

HOVEY, WILLIAMS, TIMMONS & COLLINS

By

RDH:mmm
encls.

(Docket No. 27316)

MARK: FUSOGARD

CLASS: 5

TO THE ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS:

IMMTECH BIOLOGICS, LLC, a Kansas limited liability corporation,

Business Address: 8600 W. 239, Bucyrus, Kansas 66013

Applicant requests registration of the above identified trademark mark shown in the accompanying drawing in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. 1051 et. seq., as amended) for the following goods:

ANIMAL VACCINES

Applicant is using the mark in commerce on or in connection with the above identified goods. (15 U.S.C. 1051(a), as amended). Three specimens showing the mark as used in commerce are submitted with this application.

Date of first use of the mark anywhere: during June, 1998

Date of first use of the mark in commerce which the U.S. Congress may regulate: during June, 1998

Type of commerce: Interstate

The mark is used by applying it to labels affixed to the containers for the goods.

Applicant hereby appoints the law firm of HOVEY, WILLIAMS, TIMMONS & COLLINS, 2405 Grand Boulevard, Suite 400, Kansas City, Missouri 64108, telephone number 816-474-9050 as the address to whom all communications about this application are to be directed, and hereby appoints each of the following attorneys associated with said firm, and of the same address, individually and collectively, its attorneys, with full power of substitution and revocation, to prosecute this application to register, to transact all business in the Patent and Trademark Office in connection therewith, and to receive the certificate of registration: Robert D. Hovey, Warren N. Williams, Stephen D. Timmons, John M. Collins, Thomas H. Van Hoozer, Thomas B. Luebbering, Andrew G. Colombo, Kyle L. Elliott and Tracy L. Bornman.

DECLARATION

The undersigned being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares that he is properly authorized to execute this application on behalf of the applicant; he believes the applicant to be the owner of the mark sought to be registered, or, if the application is being filed under 15 U.S.C. 1051(b), he believes applicant to be entitled to use such mark in commerce; to the best of his knowledge and belief no other person, firm, corporation, or association has the right to use the above identified mark in commerce, either in the identical form thereof or in such near

resemblance thereto as to be likely, when used on or in connection with the goods or services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his own knowledge are true and all statements made on information and belief are believed to be true.

IMMTECH BIOLOGICS, LLC

By: _____
Gary Anderson, President

Date: 27 May 1999

(Docket No. 27316)

BEST AVAILABLE COPY

75721668

FUSOBACTERIUM NECROPHORUM BACTERIN

FUSOGARD

IMM TECH

125 Dose/250 ml

FOR VETERINARY USE ONLY

For the vaccination of healthy cattle six months of age or older as an aid in the reduction of clinical signs of footrot caused by Fusobacterium necrophorum. Contains chemically inactivated culture of F. necrophorum and Suprimm™ adjuvant.

PRECAUTIONS: Refrigerate at 2-7°C. Shake thoroughly before use. Use entire contents when first opened. Do not vaccinate within 60 days of slaughter. In case of anaphylactoid reaction, administer epinephrine.

DOSAGE AND ADMINISTRATION: Inject 2 ml subcutaneously with a second dose 3 weeks later.

Manufactured by:
ImmTech Biologics, LLC
Bucyrus, KS 66013
U.S. Vet. License No. 480

Serial No.

Expiration Date:

FUSOBACTERIUM NECROPHORUM BACTERIN

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